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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,554	11/03/2000	Lawrence Friedhoff	0200-0004	4555

7590

03/27/2002

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/27/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/704,554

Applicant(s)

FRIEDHOFF ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,8.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 9.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on January 3, 2002 in Paper No. 7 wherein claims 34-35 had been added and claims 1-35 have been cancelled, and claims 36-59 are newly submitted. Currently, claims 36-59 are pending in this application.

Applicant's remarks and amendment filed on January 3, 2002 in Paper No. 7 with respect to the objection to claims 9-16 made under 37 CFR 1.75 (c) for improper dependent of record stated in the Office Action dated July 3, 2001 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment filed on January 3, 2002 in Paper No. 7 with respect to the rejection of claims 1-28 and 33 made under 35 U.S.C. 112 second paragraph for the use of the expressions "APP" of record stated in the Office Action dated July 3, 2001 has been fully considered and found persuasive to remove the rejection.

Applicant's remarks filed on January 3, 2002 in Paper No. 7 with respect to the rejection of claim 33 made under 35 U.S.C. 102(b) as being anticipated by Simons et al. for reasons of record stated in the Office Action dated July 3, 2001 have been considered and are found persuasive to remove this particular rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scolnick (WO 95/06470) in view of Sabbagh et al. and May essentially for reasons of record stated in the Office Action dated July 3, 2001.

Applicant's remarks filed on January 3, 2002 in Paper No. 7 with respect to the rejection of claims 1-28 and 33 made under 35 U.S.C. 103(a) as being unpatentable over Scolnick in view of Sabbagh et al. and May of record stated in the previous Office Action (July 3, 2001) have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant arguments that "the cited references do not suggest or otherwise obvious to a person of ordinary skill in the art that the administration of a HMG-CoA reductase inhibitor can successfully be used for treating APP processing disorders", and that "at best, the cited references, in combination, would make such treatment of APP processing disorders 'obvious to try' ", are not found convincing. As discussed in the previous Office Action, Scolnick clearly discloses that HMG-CoA reductase inhibitor such as lovastatin, simvastatin, pravastatin, and fluvastatin is useful in a method of treating Alzheimer's disease in a human. Alzheimer's disease is a known APP

processing disorder in a mammal according to Sabbagh et al. and May. Applicant's admission regarding the prior art in the specification at page 1 lines 10-11 also teaches that Alzheimer's disease is an APP processing disorder. Therefore, one having ordinary skill in the art would have reasonably expected that HMG-CoA reductase inhibitors would exhibit their known therapeutic effect in an APP processing disorder such as Alzheimer's disease. Therefore, the claimed invention is clearly obvious in view of the cited prior art.

Applicant's data shown in the Examples 1-5 of the specification at pages 35-46 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. These results demonstrate the effects on APP processing and A $\beta$  peptide formation as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

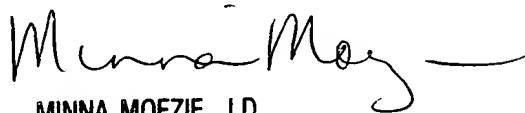
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
March 20, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600